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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,022	03/22/2004	Jeffrey S. Kiel	455-024	1967

1009 7590 09/15/2004

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EXAMINER

REYES, HECTOR M

ART UNIT PAPER NUMBER

1625

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/806,022	<b>Applicant(s)</b> KIEL ET AL.	
	<b>Examiner</b> Hector M Reyes	<b>Art Unit</b> 1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of The Claims**

Claims 1-21 are currently under Examination.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are indefinite and ambiguous because while claiming a chemical composition, they only identify a chemical compound. A chemical composition requires at least two compounds as essential elements. What is the second essential element of the claimed composition?

Claim 3 recites the phrase "A chemical compound consisting essentially of gabapentin tannate". The said phrase is indefinite because a chemical compound cannot consist of anything else but the compound itself.

Claim 4 recites the phrase "The chemical compound of claim 1". The said phrase is confusing since claim 1 is not drawn to a chemical compound if not to a chemical composition, which requires at least two chemical compounds. Clarification is requested.

Claim 5 recites the phrase "A method of synthesizing a chemical compound" nonetheless it is unclear what chemical compound is the target intended to be prepared,

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therefore the said claims lacks clarity and definition. Is applicant intended to prepare gabapentin tannate only or any possible organic compound?

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Satzinger et al, US 4024175 in view of Gould, International Journal of Pharmaceutics, vol. 33 (1986) pp 201-217.

Satzinger discloses the preparation of gabapentin and pharmacological compatible salts, see column 1, lines 1-11, methods for preparing the same, see Examples 1-12 and pharmaceutical compositions comprising the said salts, see for instance column 3, lines 48-54.

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Regarding the nature of the salts, Satzinger discloses that “ since amino acid are amphoteric, pharmacologically compatible salts of appropriate inorganic and organic acids, for example hydrochloric acid, sulphuric acid, phosphoric acid, acetic acid, oxalic acid, lactic acid, citric acid, malic acid, salicylic acid, malonic acid, maleic acid, succinic acid ..., see column 2, lines 1-15.

Satzinger however does not disclose the preparation of gabapentin salts wherein the anion is tannate.

Gould discloses basics details of salts selection for basic drugs and wherein some anions are pointed out some anions that have been FDA-Approved for commercially marketed drugs. For instance, tannate, hydrochloride, sulfate and maleate, are among the said anions, see page 202, Table I.

Thus, a person skill in the art at the time that the invention was made would be motivated to prepare tannate salts of the very well known drug gabapentin by following the salt-preparation's method outlined by Satzinger in order to prepare any salts of gabapentin, but using tannate as the salt-anion and to further expect that the said salts would be used in pharmaceutical compositions. Notice that Satzinger does not limit the gabapentin salts to the particular examples presented and that Applicants has not presented any unexpected results resulting from the tannate salt in contrast to the already known gabapentin. The interchange of an anion already recognized as FDA-approved in marketed drugs by another in order to obtain the salts predicted by a known method and to further use the said salt in pharmaceutical compositions is within the capabilities of those skilled in the art.

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**CONCLUSION**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hector M. Reyes, whose telephone number is (571) 272-0691. The Examiner can normally be reached Monday through Friday from 9:30 to 5:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Ms. Rita Desai can be reached at (571) 272-0684.

Hector M. Reyes, PhD JD  
Reg # P-54,846  
AU 1625  
September 13, 2004

*RDesai*  
*9/13/04*